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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,078	07/25/2001	William F. Wade	PM	7302

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,078	WADE ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.
Applicant's submission filed on 9/13/05 has been entered.

Applicant's amendment, filed 9/13/05, is acknowledged.
Claims 2-4. 6-11 and 16-30 had been canceled.
Claim 1 had been amended.

In response to the Notice of Non-Compliance, mailed 11/29/05, applicant's amendment, filed 12/21/05, has been entered.
Claims 1-31 have been canceled.
Claims 32-37 have been added.

Claims 32-37 are pending and being acted upon presently.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 32-37 are rejected under 35 U.S.C.§ 103(a) as being unpatentable over Anand et al. (US 6,291,208 B1) and Heath (US 2002/0135722 A1) in view of Maraskovsky et al. (U.S. Patent No. 6,497,876) and Smith et al. (U.S. Patent No. 6,509,313)_

Applicant's arguments, filed 11/29/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant's asserts that the prior art of record was drawn to the use of anti-CD40 antibody conjugates in the absence of adjuvants, wherein the newly added claims do include adjuvants.

Although it is acknowledged that the prior art primary references do focus on the use of the described anti-CD40 antibody conjugates in the absence of adjuvants, the following is also noted.

As acknowledged previously by applicant, Anand et al. teach the use of antibody conjugates comprising antibodies that bind antigen presenting cells, including dendritic cells to deliver antigens in order to generate immunogenic compositions to a variety of antigens that Heath teaches the co-administration of a CD40 stimulating moiety as an adjuvant in combination with an antigen.

Maraskovsky et al. has been added to provide additional teaching that for use in stimulating certain type of immune responses, administration of other cytokines along with antigen-pulsed dendritic cells (e.g. see Summary of the Invention, including column 2, paragraph 2 and Detailed Description, including column 11, paragraphs 3-4) (see entire document). It is noted that the dendritic antigen presenting dendritic cells taught by Maraskovsky et al. include stimulation via CD40, albeit via CD40L rather than the claimed anti-CD40 antibodies. In either case, clearly Maraskovsky et al. teach the presence of CD40 on antigen presenting cells, which can be targeted as well as the use of cytokines as adjuvants in efforts to enhance immune responses to antigens of interest at the time the invention was made.

Note, too, that the teaching of Heath indicates that the anti-CD40 antibody was an adjuvant in their system.

Also, note that Anand et al. teach that the recombinant conjugate when administered without an extrinsic adjuvant elicit good priming, but faded after a while and needed to be boosted (e.g. see column 8, paragraph 3).

Therefore, while Anand et al. does teach enhancing immune responses in the absence of conventional adjuvants, this teaching does not preclude the ordinary artisan to apply adjuvants, including combinations of certain types of adjuvants, such as cytokines, in boosting immune responses to antigens of interest.

For example, the prior art clearly provides for combination of cytokines in enhancing immune responses, as evidenced by Maraskovsky et al. (see Summary of the Invention, including column 2, paragraph 2 and Detailed Description, including column 11, paragraphs 3-4)

In addition, Smith has been provided to support he use of activating immune responses with cytokines, including combinations of cytokines to boost immune responses in the absence of toxicity (see entire document, Summary of the Invention and Detailed Description of the Invention).

Again, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller , 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

Again, in contrast to applicant's assertions concerning that the prior art does not meet the elements of the claims the following of record is reiterated for applicant's convenience.

Anand et al. teach the use of antibody conjugates comprising antibodies that bind antigen presenting cells, including dendritic cells (e.g. column 2, paragraphs 4 and 6), to deliver antigens in order to generate immunogenic compositions to a variety of antigens (e.g. column 7, paragraph 2) (see entire document, including Summary of the Invention and General Description of the Invention). Anand et al. Teach that these is applicable to any antigen which it is desired to target to antigen presenting cells, including antigens derived from viruses, bacteria and tumors (see column 7, paragraph 1)

Heath teaches the co-administration of a CD40 stimulating moiety (e.g. anti-CD40 antibodies) (e.g., see paragraphs 0055, 0061, 0062) and the appropriate antigen, including the use of covalent linkage or co-entrapment as a vaccine (e.g. see paragraphs 0026-0027 and 0029) to a variety of antigens (see entire document, including Summary of the Invention).

Maraskovsky et al. has been added to provide additional teaching that for use in stimulating certain type of immune responses, administration of other cytokines along with antigen-pulsed dendritic cells (e.g. see Summary of the Invention, including column 2, paragraph 2 and Detailed Description, including column 11, paragraphs 3-4) (see entire document). It is noted that the dendritic antigen presenting dendritic cells taught by Maraskovsky et al. include stimulation via CD40, albeit via CD40L rather than the claimed anti-CD40 antibodies. In either case, clearly Maraskovsky et al. teach the presence of CD40 on antigen presenting cells, which can be targeted as well as the use of cytokines as adjuvants in efforts to enhance immune responses to antigens of interest at the time the invention was made.

The prior art clearly provides for combination of cytokines in enhancing immune responses, as evidenced by newly added Maraskovsky et al. (see Summary of the Invention, including column 2, paragraph 2 and Detailed Description, including column 11, paragraphs 3-4)

In addition, Smith has been provided to support he use of activating immune responses with cytokines, including combinations of cytokines to boost immune responses in the absence of toxicity (see entire document, Summary of the Invention and Detailed Description of the Invention).

Also, it has been noted that Anand et al. teach that the quantity to be administered depends on the subject to be treated, including the capacity of the individual's immune-system to synthesize antibodies and to produce a cell-mediated immune response (column 9, paragraph 1).

Given the teachings of Heath to provide anti-CD40 with antigen in composition form or as a conjugate (see Summary of the Invention) and the teachings of Anand et al. to provide antigen with anti-antigen presenting cell / dendritic cell antibodies; it would have been obvious to one of ordinary skill in the art to administer the antigen in the context of such antigen-antibody conjugate with the immunostimulatory anti-CD40 antibodies to boost the immune response to a wide variety of desired antigens, including providing both components in the same composition, as taught by Heath (see paragraphs 0026-0027 and 0029).

In addition, the motivation to combine the prior art can arise from the expectation that the prior art elements will perform their expected function to achieve their expected results when combined for their common known purpose. Here, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine both antigen-antibody conjugates for dendritic cells and CD40-specific antibodies to target antigens to the antigen presenting cells of interest, including CD40-expressing antigen presenting cells, as well as to enhance the immunogenicity of said antigens.

Given the teachings of Anand et al. and Heath; the ordinary artisan would have been motivated to target professional antigen presenting cells such as dendritic cells with the combination of antigen-antibody targets and the immunostimulatory agonistic CD40 antibodies to enhance the immune response to a wide variety of antigens. As routinely practiced at the time the invention was made, adjuvants were employed to boost immune responses to antigens of interest. Both Maraskovksy et al. and Smith teach the known use of cytokines to boost immune responses to antigens of interest, including the advantages of using cytokines in low toxicity formulations, consistent with the teachings of Heath, who teaches advantages of low toxicity formulations of anti-CD40 immunoconjugates in boosting immune responses. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments are not found persuasive.

5. No claim allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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